

Aurorix[®]

M

Meda

Filmdragerad tablett 300 mg

Avregistreringsdatum: 2021-07-14 (Tillhandahålls ej) (14,7×7,7 mm, vit, oval, bikonvex, med brytskåra, märkta 300)

Antidepressivum, MAO-hämmare

Aktiv substans:

Moklobemid

ATC-kod:

N06AG02

För information om det avregistrerade läkemedlet omfattas av Läkemedelsförsäkringen, kontakta Läkemedelsförsäkringen.

Läs mer om avregistrerade läkemedel

Miljöpåverkan

Moklobemid

Miljörisk: Risk för miljöpåverkan av moklobemid kan inte uteslutas då ekotoxikologiska data saknas.

Nedbrytning: Det kan inte uteslutas att moklobemid är persistent, då data saknas.

Bioackumulering: Moclobemid har låg potential att bioackumuleras.

Detaljerad miljöinformation

Environmental Risk Classification

Predicted Environmental Concentration (PEC)

PEC is calculated according to the following formula:

$$\text{PEC}(\mu\text{g/L}) = (A \cdot 10^9 \cdot (100 - R)) / (365 \cdot P \cdot V \cdot D \cdot 100) = 1.5 \cdot 10^{-6} \cdot A(100 - R)$$

$$\text{PEC} = 5.637 \cdot 10^{-3} \mu\text{g/L}$$

Where:

A = 37.58 kg (total amount API of moclobemide in Sweden year 2020, data from IQVIA) (Ref. 1)

R = removal rate = 0% (no data available)

P = number of inhabitants in Sweden = $10 \cdot 10^6$

V (L/day) = volume of waste water per capita and day = 200 (ECHA default) (Ref. 2)

D = factor for dilution of waste water by surface water flow = 10 (ECHA default) (Ref. 2)

Ecotoxicological studies

No ecotoxicological data available.

Degradation

No degradation data available.

Bioaccumulation

Estimated Log P_{ow} values of 1.56 (ALOGPS) and 1.45 (ChemAxon) (Ref. 3) indicates that moclobemide has low potential for bioaccumulation.

$\text{Log } P_{ow} < 4$ which justifies use of the phrase “Moclobemide has low potential for bioaccumulation”.

Excretion (metabolism)

Less than 1% of given dose of moclobemide is found in unchanged form in the urine. (Ref. 4)

References:

1. Data from IQVIA "Consumption assessment in kg for input to environmental classification - updated 2021 (data 2020)".
2. ECHA, European Chemicals Agency. Guidance on information requirements and chemical safety assessment. Ver 2.1, 2011.
3. DrugBank, Drug and Drug Target Database, www.drugbank.ca
4. SPC (Summary of Product Characteristics) for Aurorix, 2014-08-19, www.fass.se